Attorney Docket No.: 20518/14
Client Reference No. M-1096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Yerlikaya et al.	**EXAMINER:**	Mirellys Jagan
SERIAL NO.:	09/942,334	**ART UNIT:**	2859
FILED:	August 28, 2001	**CONFIRMATION NO.:**	7702
FOR:	TEMPERATURE PROBE ADAPTER		

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

Date: August 17, 2004

By: Marilyn R. Bogus
Marilyn R. Bogus

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT/DECLARATION OF PRIOR INVENTION UNDER 37 C.F.R. § 1.131

I, Y. Denis Yerlikaya, declare:

That I am a citizen of the United States and reside at 13257 Kenroyal Drive, St. Louis, Missouri.

That I am one of the co-inventors in the above-identified patent application.

That I am familiar with the above-identified U.S. Patent Application Serial No. 09/942,334 and with U.S. Patent Application Publication No. 2002/0181545 to Babkes cited by the Examiner.

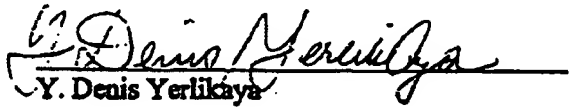
That I conceived of and/or co-invented and reduced to practice in the United States the subject matter claimed in U.S. Patent Application Serial No. 09/942,334 prior to May 29, 2001, the filing date of U.S. Patent Application Publication No. 2002/0181545 to Babkes.

The attached **Exhibit A** is a copy of an invention disclosure form describing an iso-chamber as a portable frame, which carries both the patient temperature probe and a cardboard box containing the disposable plastic probe tips. The invention disclosure form includes a set of sketches and drawings which I made prior to May 29, 2001 showing the removable module, temperature calculating unit and connector mounted EEPROM.

That **Exhibit A** describes and proves conception and reduction to practice of each of the claims in U.S. Patent Application Serial No. 09/942,334 prior to May 29, 2001.

That the undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements an the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

So declared by:

Signed: 
Y. Denis Yerlikaya

Date: August 17, 2004

#1283609 - 20518/14

KENDALL

M-1096

INVENTION DISCLOSURE

"Supplement to Docket No. M-1096 [redacted]

Date Typed: [redacted]

1. **Title or Subject of Invention:** Use of a Chip Scale Package EEPROM IC for Probe Temperature (Refer to Page I)

2. **Name(s) of Inventor(s):** Y. Denis Yerlikaya

3. **Sherwood-Davis & Geck Division:** R&D - Medical Products

4. R&D Project No.: 4146

5. **Detailed Description of the Invention:** (Describe purpose, structure, operation, if an apparatus or article; describe steps, conditions and results, if a process; give components, proportion and synthesis, if composition of matter. Attach dated blueprints, sketches and/or photographs, if available and appropriate. This description should enable a person not familiar with the subject matter to understand the invention. If a supplementary sheet is required, it should be signed, dated, and referenced herein.):

The main purpose of this invention is to design a state-of-the-art Fast Temp Thermometer System that would effectively reduce patient exposure to various sources of cross-contamination by using an instantly detectable and identifiable isolated chamber-based, accurate, fast, easily and accurately calibrated and affordable temperature probe sub-system. The following description will explain the way this invention allows all these performance enhancing features simply by using a parasite power 256 bit Single Wire EEPROM IC embedded in the probe cable connector.

The Parasite Power 256 Bit Single Wire Communicating 1-Wire EEPROM IC will be soldered onto a small PCB which will be placed inside the instrument end connector of the coil cord of the probe and will be overmolded and covered with strain relief. The data line of the EEPROM will be directly connected to a single port pin of the thermometer microprocessor. Since it will receive its power from the same data line, it will not require any other power supply connection. It will communicate with the microprocessor at up to 16.3K bits per second. Upon power up, the microprocessor will automatically read the unique, factory-laser programmed and validated 64-bit registration number to assure absolute identity of the probe and then will read the additional pre-stored 256-bit calibration and algorithm parameters which characterize only that particular probe tip sensor.

Refer to Page I and II, Item 5 and the Lab Book Record and DS2430AX 1-Wire EEPROM data sheets for details.

6. **Advantages of the invention over such prior practice:**

• Provides a means of instant identification of a mobile iso-chamber based temperature probe. Since the patient probe is an integral part of the iso-chamber, all cross contamination possibilities listed in the Attorney Docket No. M 1022 will be eliminated.

Refer to Page II Item 6 for details

7. **Conception Date:** (Give day, month and year that idea for invention was conceived and specify records relied on.)

[redacted]

8. **Earliest Sketch:** (Identify earliest sketch or drawing and provide copy, if available.)

[redacted]

9. **Reduction to Practice:** (Identify earliest date that invention was operated, produced and/or used and state details as to extent and place, and give names of any witnesses present.)

By using various DS2430AX 1-Wire EEPROM samples, the EEPROM Programming (data read and data write) was Completed on [redacted]

10. Prior Disclosure: (Identify any disclosure, demonstration or showing of the invention by any mode to anyone not employed by Sherwood and state when and to whom, whether confidential or not, and identify any records relie
None

11. Test or Manufacture: (Identify date of any past or scheduled clinical or marketing testing and/or manufacturing release.)
Initial Testing was completed during the month o[redacted]

SIGNATURE(S) of INVENTOR(S)

Inventor: Y. Denis Yerlikaya (Signature) Date: [redacted]

(Type or print name): Y. DENIS YERLIKAYA Citizenship: U.S.

Residence

Address: 13257 KENROYAL DRIVE, ST. LOUIS, MO 63131
(Street, City, County and State or Country)

Inventor: _____ (Signature) Date: _____

(Type or print name): _____ Citizenship: U.S.

Residence

Address: _____
(Street, City, County and State or Country)

Inventor: _____ (Signature) Date: _____

(Type or print name): _____ Citizenship: U.S.

Residence

Address: _____
(Street, City, County and State or Country)

WITNESSED:
The above invention disclosure has been read and understood by the following two co- workers who are not inventors.

Read and Understood Ted Klefisch Date: [redacted]

(Type or print name): TED KLEFISCH

Read and Understood [redacted] Date: [redacted]

(Type or print name): MICHAEL J. KERWIN

(Continued from Page 1, Item 1)
Calibration and Automatic Iso-Chamber-Based Probe Detection and Identification

(Continued from Page 1, Item 5)
Because of the strict cost containment of this thermometer project, one low-cost embodiment in which an RJ-45 modular plug at the end of a 5-conductor coil cord and a mating telephone jack was selected.

In this concept, one end of the cable is attached to the temperature probe. The other end has a PCB with 8 gold plated pads, 5 of which are connected to the 5 conductors of the cable, 2 of the pads are connected to the EEPROM chip, and one is unconnected. In one design approach, the PCB containing the EEPROM IC slides into the module housing and is sealed and over-molded with a strain relief (As shown in attached Tyco Electronics' sketches dated [redacted] In another approach, the portion of the PCB containing the EEPROM and the cable connections is sealed and over-molded with a strain relief (As shown in attached Kendall's sketch dated [redacted] In both approaches, the over-molded connector portion of the cable, as shown in Figures 1 and 2, is permanently attached to the wall of the mobile iso-chamber module.

The iso-chamber is a portable frame, which carries both the patient temperature probe and a cardboard box containing the disposable plastic probe tips. When the iso-chamber module is inserted into the thermometer, either the 8-gold plated contacts (in one embodiment) are mated with a standard telephone jack located on the thermometer wall, or in the other embodiment, the 8 gold-plated pads of the cable are mated with a customized sealed connector.

The feasibility study of the above listed concepts indicated that making both the cable plug and the telephone jack leak proof would create many manufacturing challenges and would increase the price of these components beyond the acceptable target cost. Since it was necessary that the thermometer system meet the CEN Standard's water resistance compliance requirement, these parts had to be designed so that they were water-resistant. After consulting various connector manufacturers, Tyco Electronics was selected as a co-developer with Kendall to complete the design of the following water-resistant cable connector and mating header assembly embodiments.

In this concept, one end of the cable is attached to the patient temperature-sensing probe. The 5 conductors at the other end of the cable are soldered on a PCB with 7 specially distributed gold pads, 5 of which are directly connected to the 5 conductors of the cable, and 2 of the pads are connected to the EEPROM IC (sketch #1 attached). The PCB slides underneath the surface of the connector housing, and the pads are aligned with 5 spring-loaded, water-resistant pogo pins which are tightly embedded into the connecting surface of the housing (sketch #2 attached). The whole connector assembly is then sealed and over-molded with the strain relief (sketch #3 attached).

The mating header assembly is designed by inserting 7 stamped metal terminal pins are inserted into a special housing and are sealed between the contacts and housing cavities

(Tyco Electronics' attached sketches dated [redacted]. This mating header assembly has water-resistant terminals and connector rims because the backend of these terminals will be soldered or interfaced with the main thermometer control board which is located behind the instrument case wall. The main criteria for designing such a connector is that it should not allow any water penetration or seepage through its terminals and rims inside the thermometer case. The header has a groove all around the body to accept and lock the mating cable connector to form an electrical connection once the iso-chamber is inserted into the thermometer.

The connector housing of the probe cable is designed so that it can be inserted and locked into the special groove of the iso-chamber. Therefore, the temperature-sensing probe with the coil cord becomes an integral part of the iso-chamber (sketches #4 and #5 attached).

The EEPROM chip which is embedded in the cable connector holds all the necessary information required for an accurate two-point calibration of the thermistor sensors located inside that particular probe tip. This information includes the calibration-related parameters such as thermistor resistor values at two different reference temperatures, the probe identification information related to type of iso-chamber-based probe (rectal or oral/axillary), unique assembly part number, date code, CRC, and other manufacturing related data.

(Continued from Page 1, Item 6)

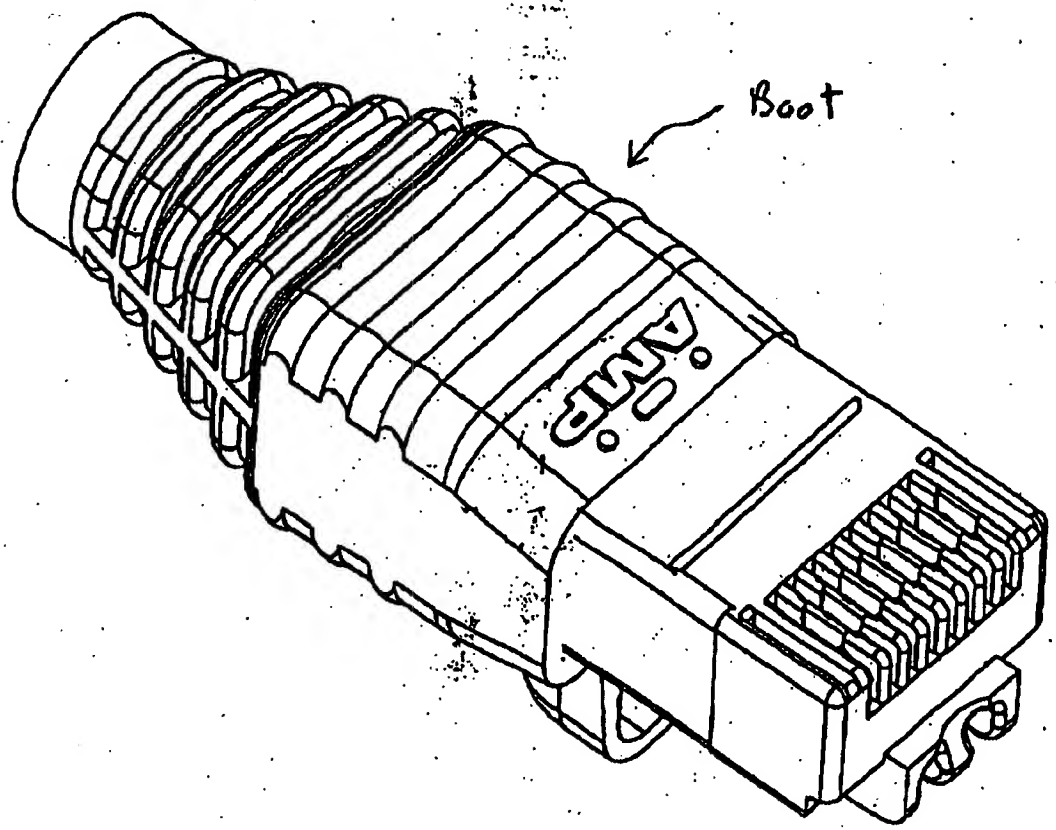
- Will facilitate effective interchangeability of different types of iso-chamber-based probes (red or blue) or different probes of the same kind, (e.g. all blue) without requiring very time consuming and skilled labor intensive hardware modification.

- Will allow the thermometer to perform better and be more accurate than the conventional art. It allows the use of more than one thermistor sensor, if necessary, and holds all calibration parameters of the thermistor sensors at the tip of the probe which are taken at least at two different reference temperatures.

- The capability of holding two reference point parameters would yield an uncompromising advantage over conventional single point systems in the following categories:

  - Reduces the linearity errors and improves the regression process through use of the software program
  - Allows the use of a lower cost, lower thermal mass thermistor chip with a looser tolerance as opposed to the conventionally used tight tolerance, expensive and bulky glass encapsulated thermistor bead, thus improving the over-all response and thermal time constant of the probe
  - Eliminates intensive labor and human error, and reduces the cost of the probe.

Final Assembly

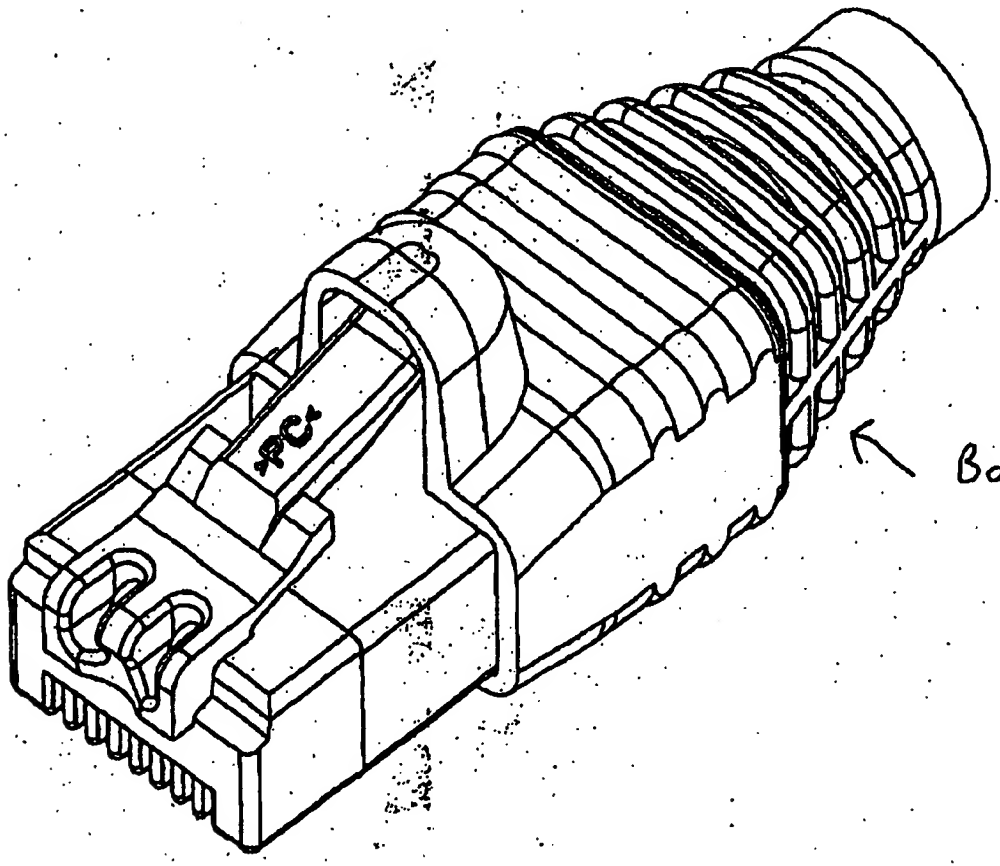


Cord not shown.

4. Lauren [redacted]

p. 4 of 4

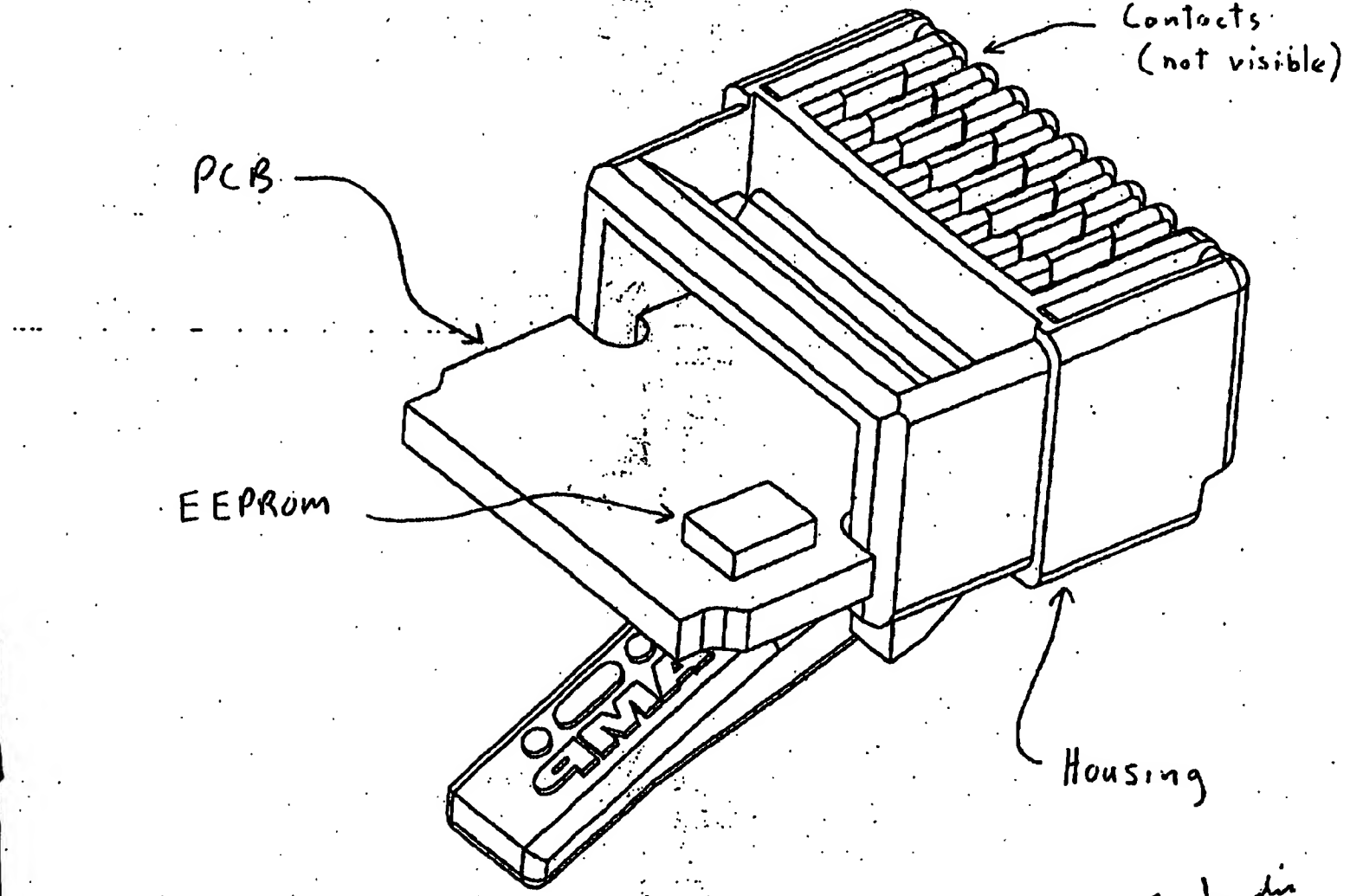
Final Assembly



Cord not shown.

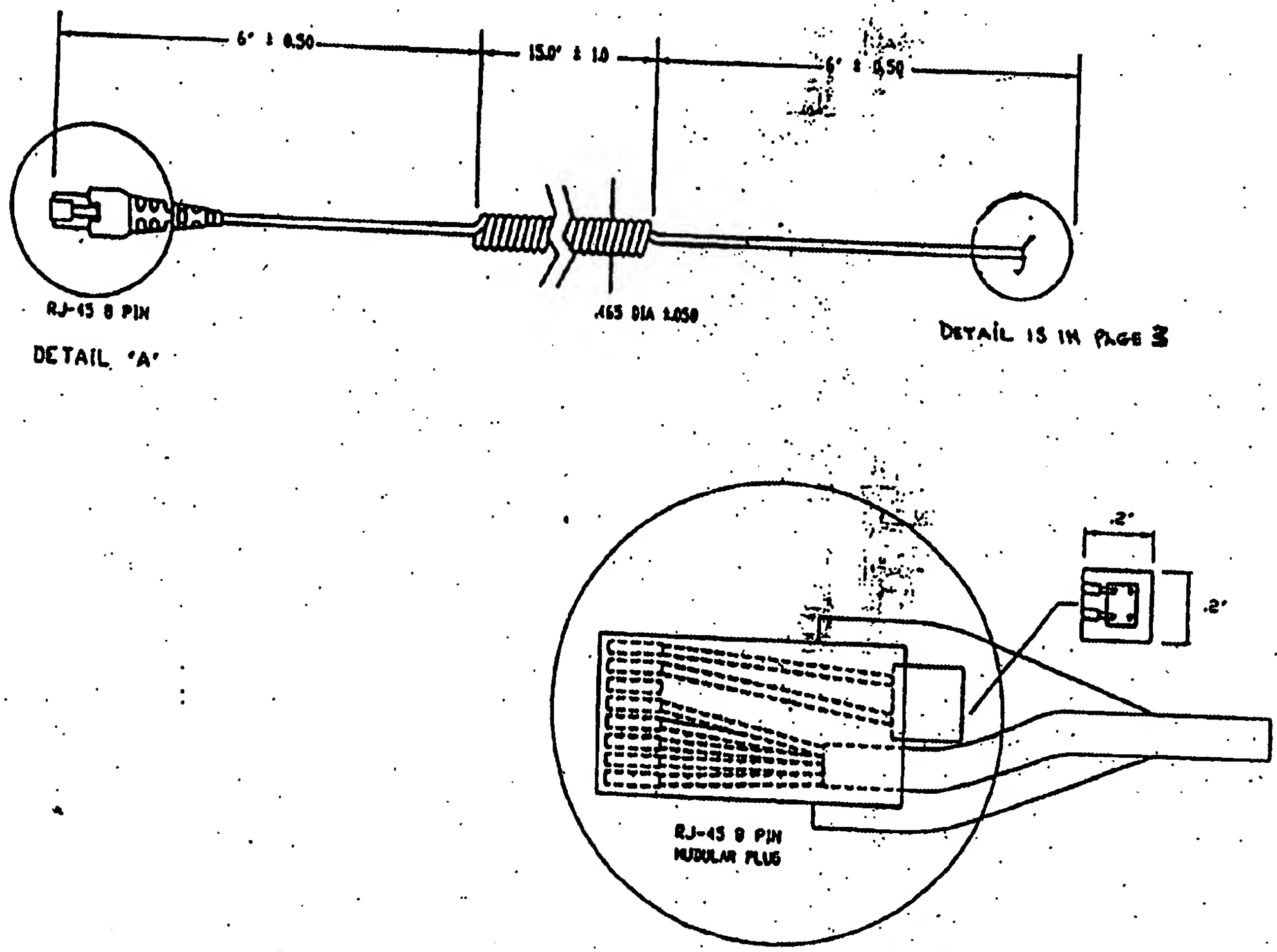
A. Landin [redacted]

Modular Plug Sub-Assembly



Coil cord conductors will be soldered or welded directly to PCB.

4. [redacted]



SHERWOOD CONFIDENTIAL

STATUS	DATE	APPD

DO NOT SCALE

KENDALL

PVC

COLOR: BLUE OR RED

[redacted]

[redacted]

1

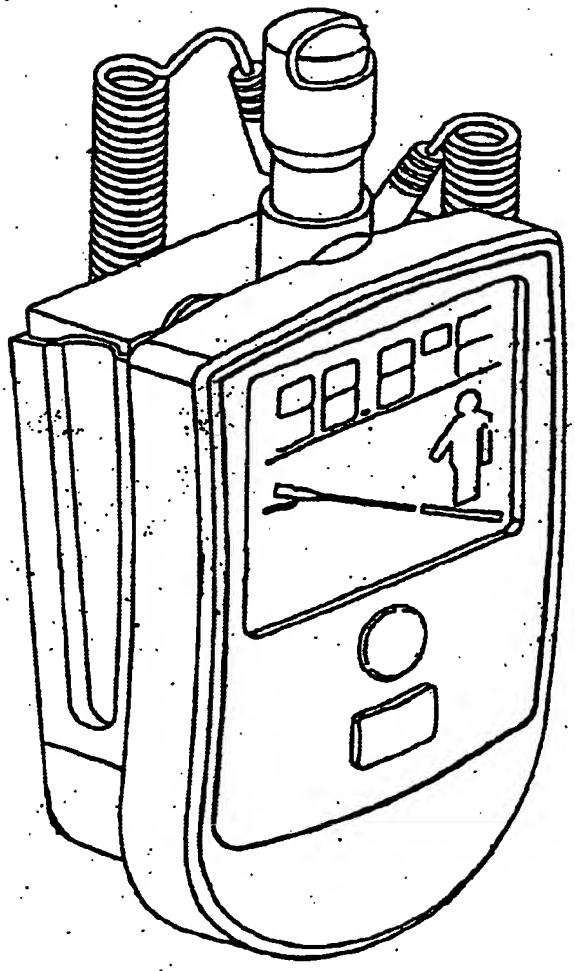


FIG. 1

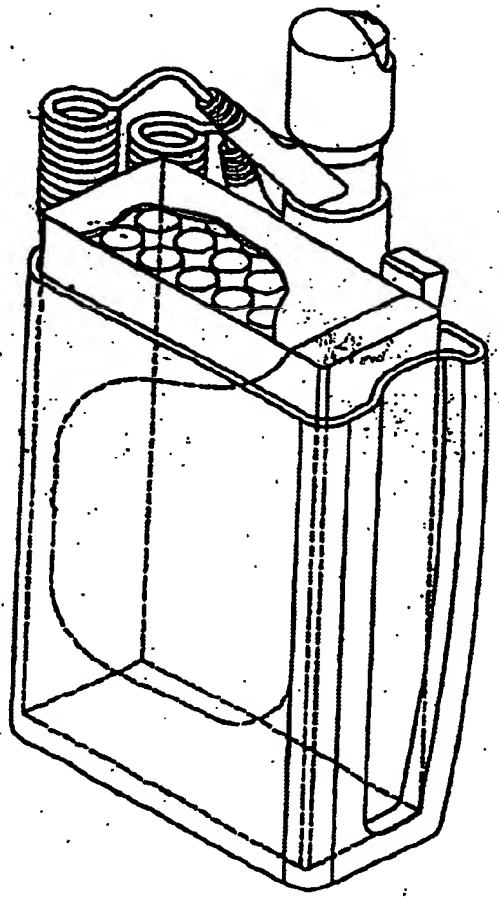
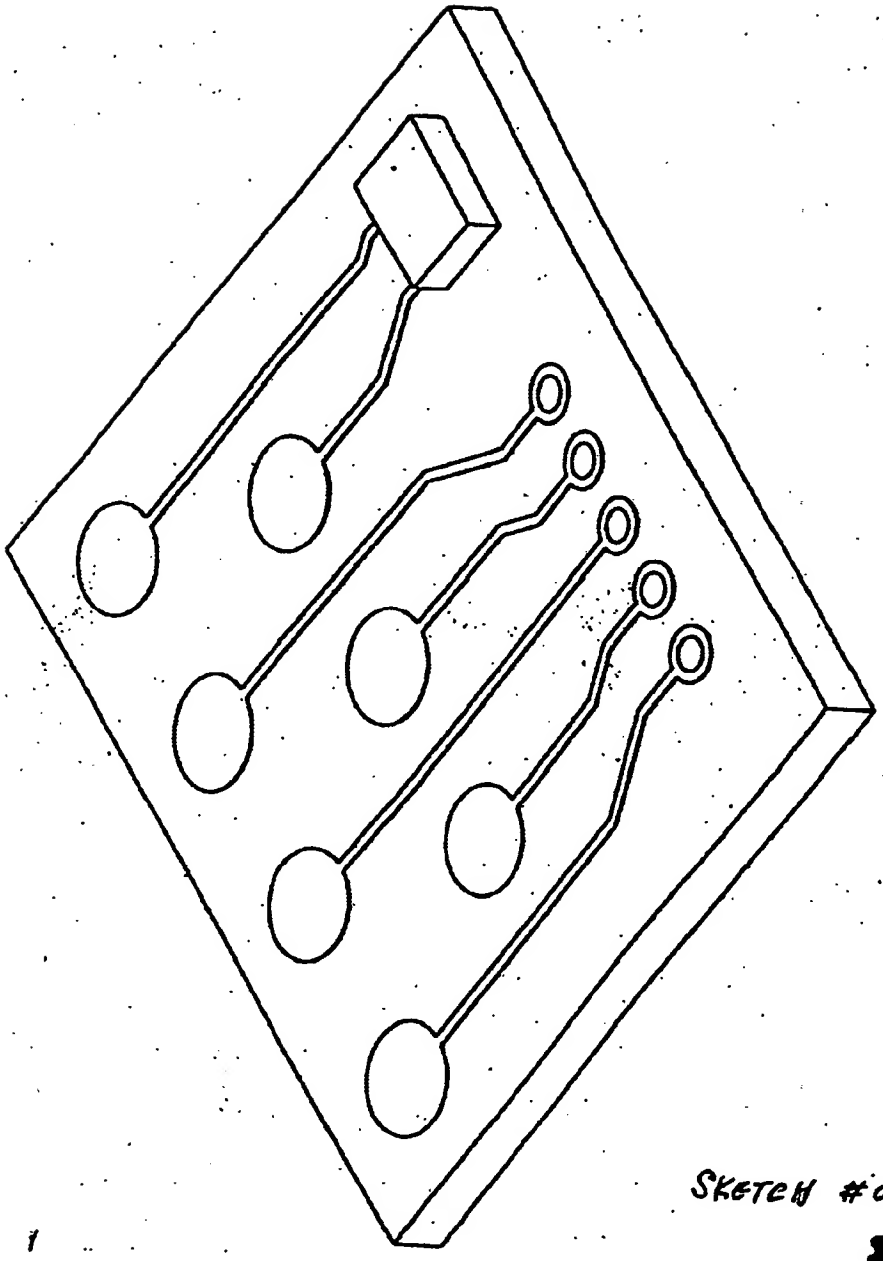


FIG. 2

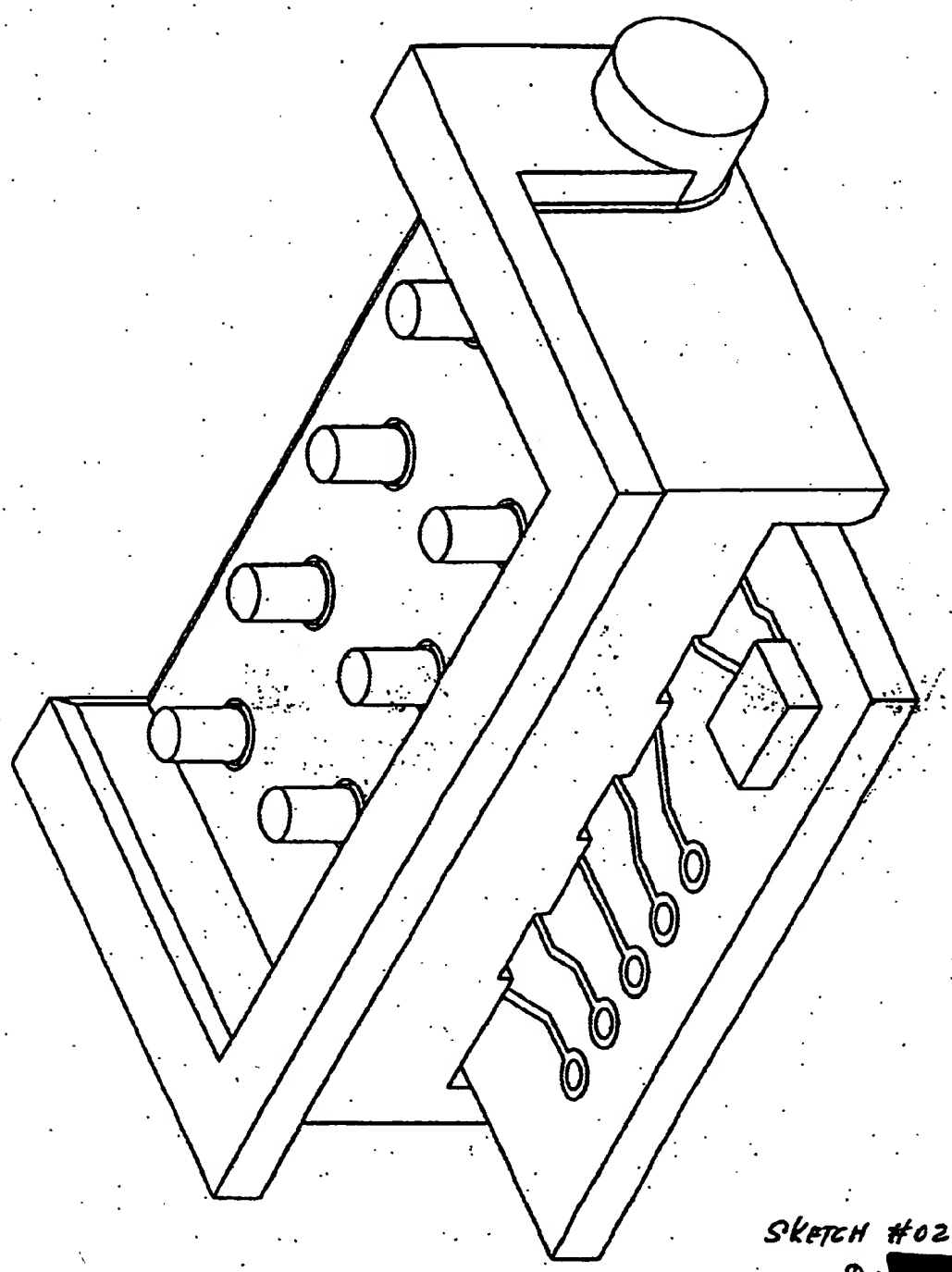
[redacted]



SKETCH #01

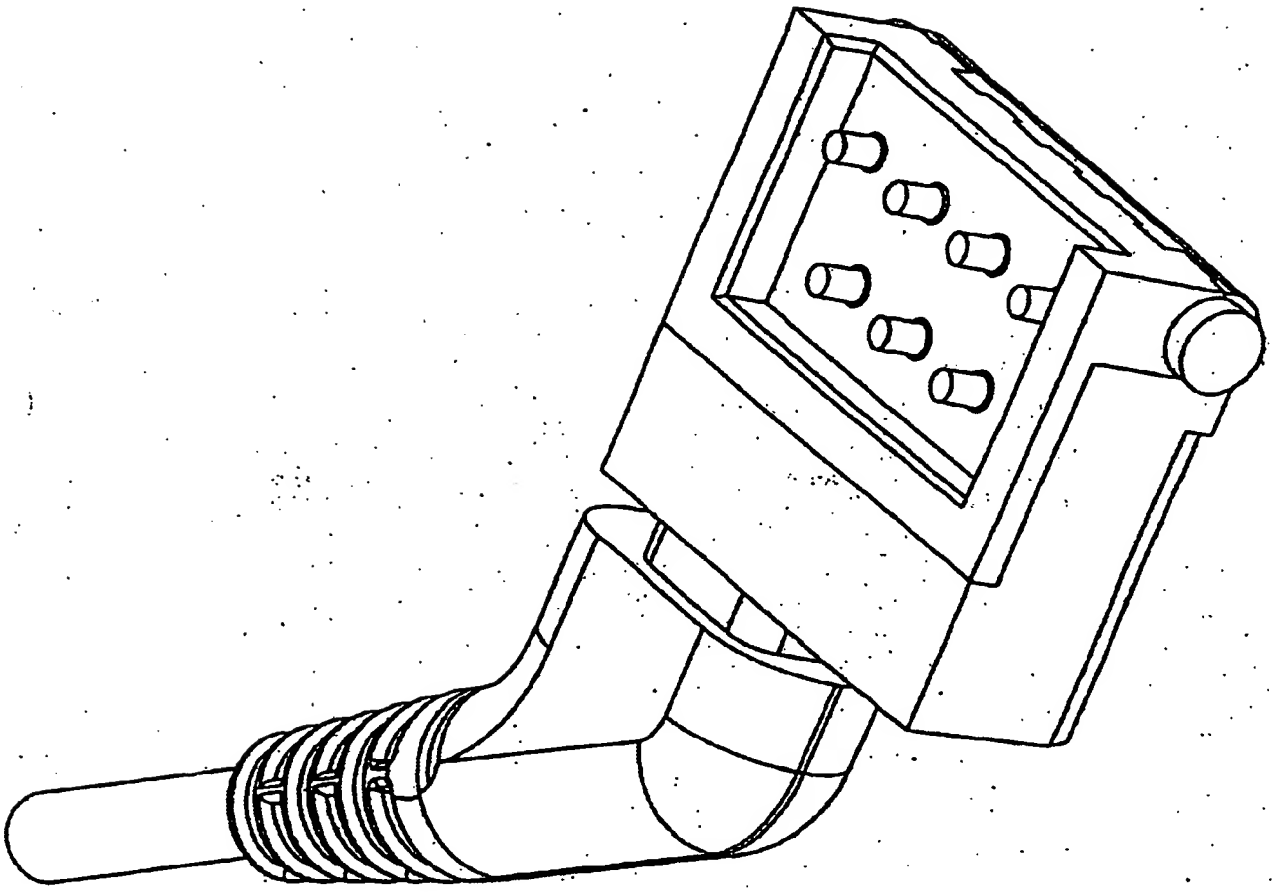
[redacted]

Dy



SKETCH #02

By [redacted]

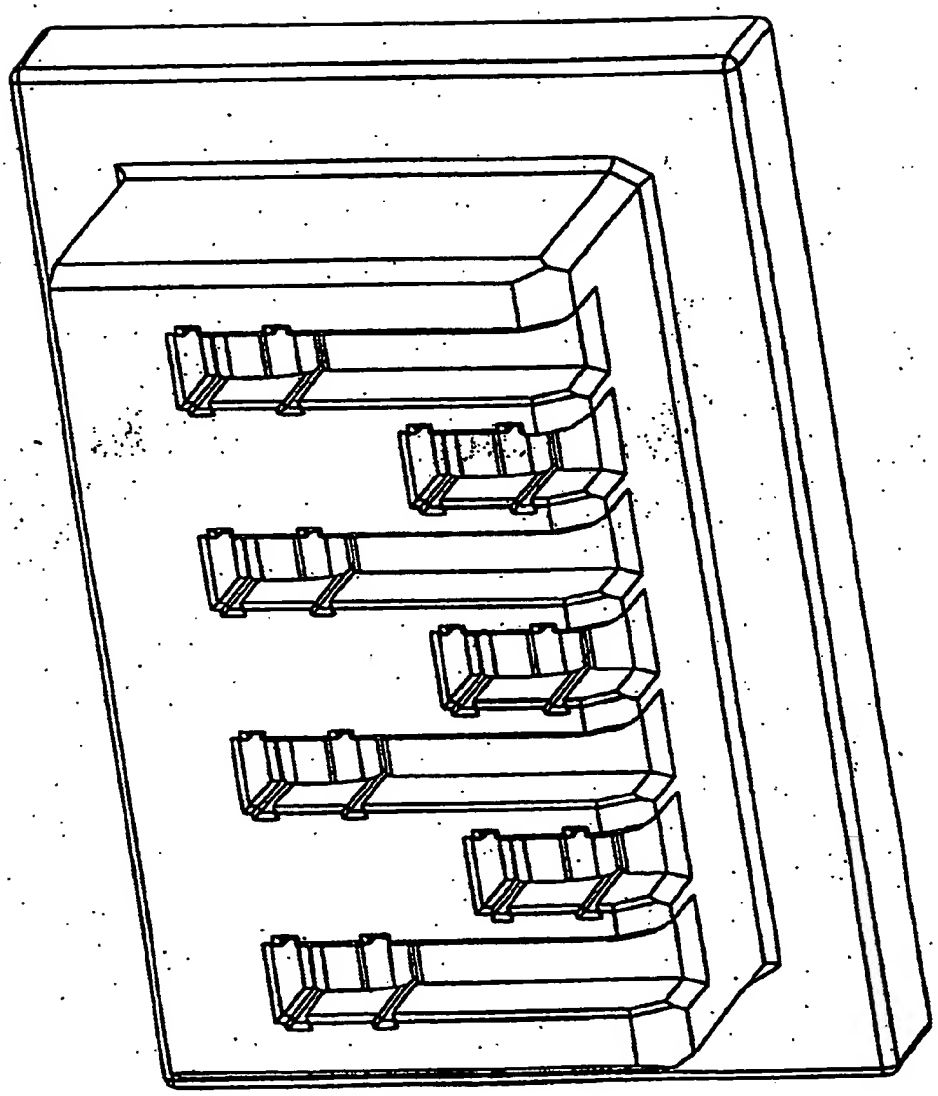


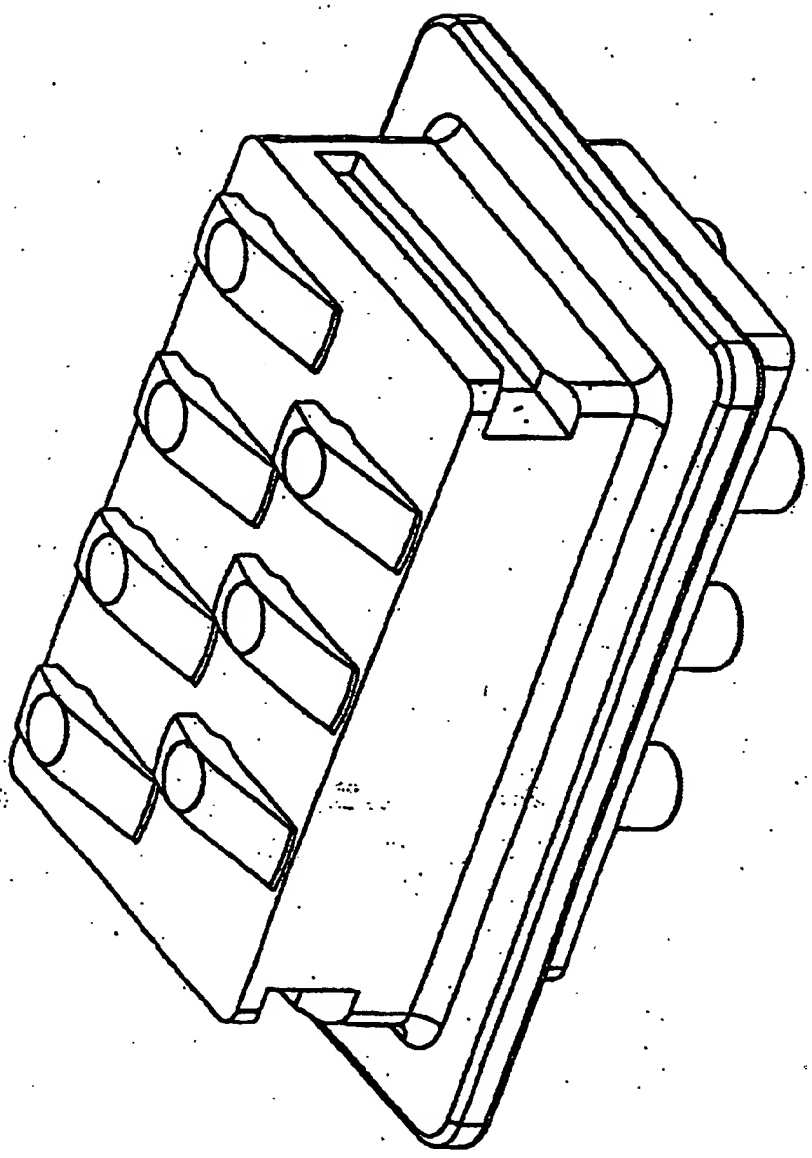
SKETCH #03

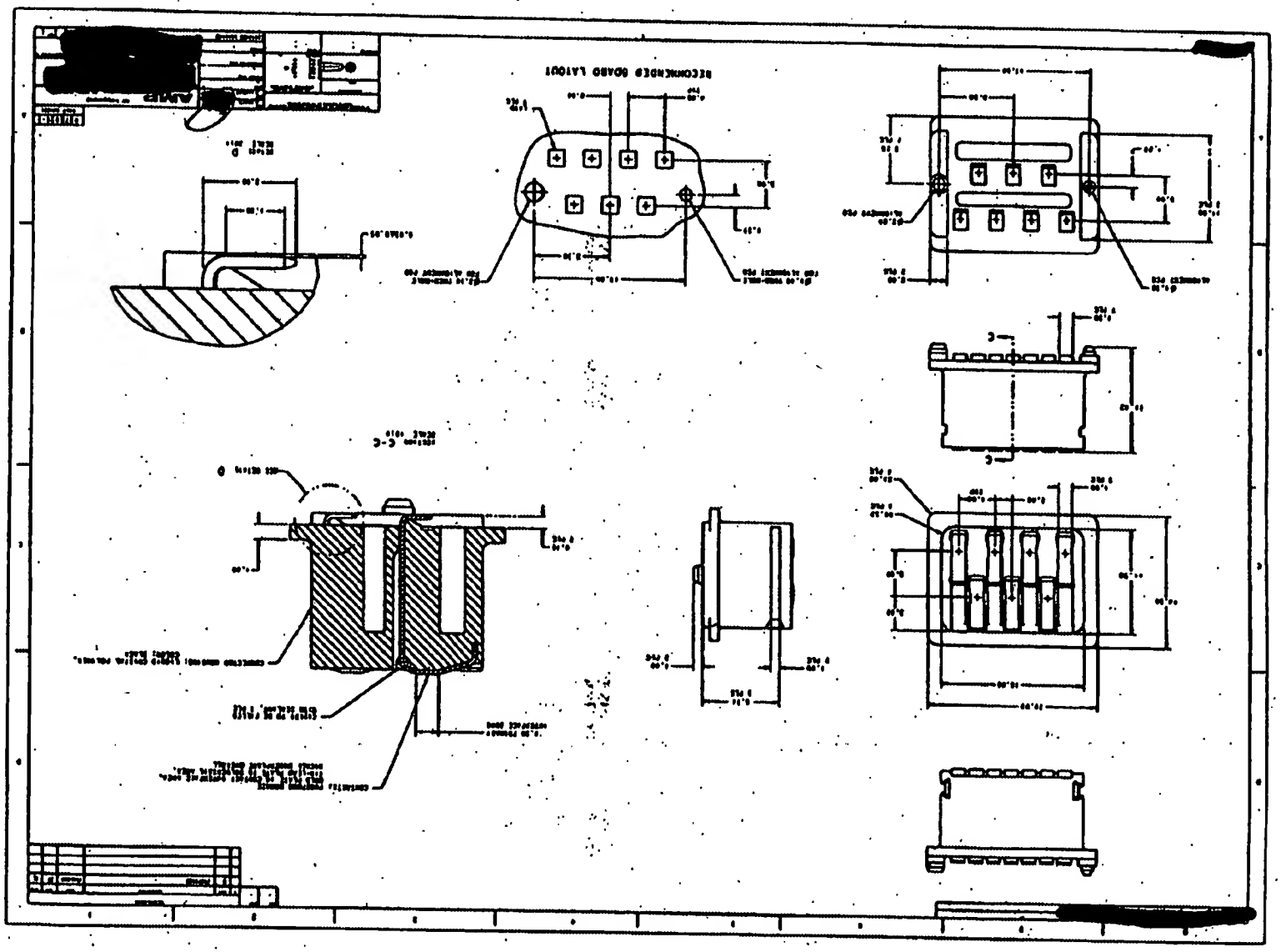
[redacted]

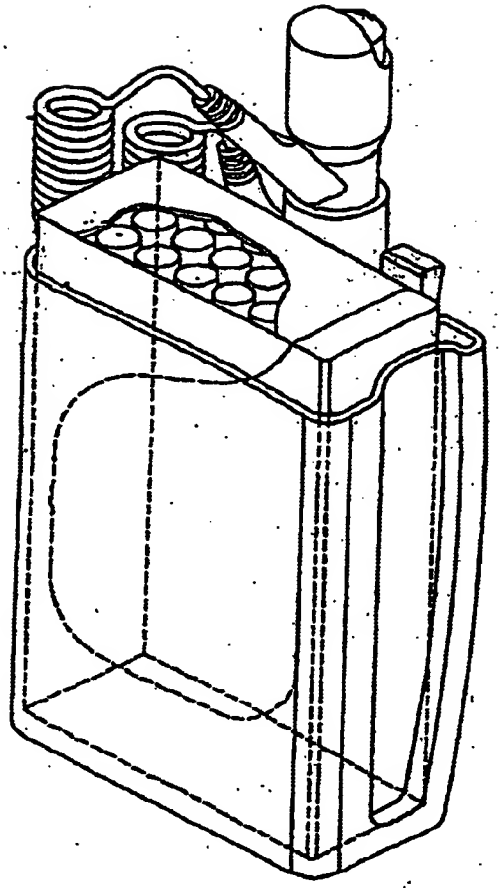
By

[redacted]





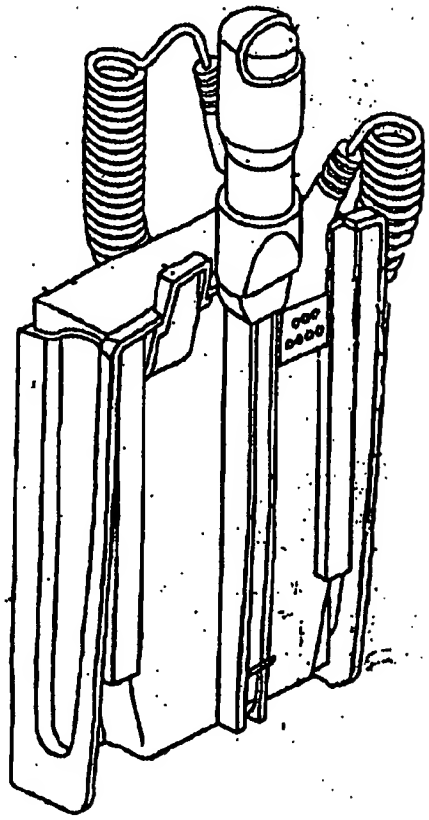




SKETCH #04

[redacted]

Dy



SKETCH #05

[redacted]

Dy